EXHIBIT A

EXPERT REPORT OF MICHAEL KEEN
IN RE BAIR HUGGER PRODUCTS LIABILITY LITIGATION

June 2, 2017

I am the Senior Director of Planning & Development at St. Michael's Hospital in Toronto, Ontario, Canada, and I have substantial expertise in the design of hospital facilities, including operating rooms. I have been retained by 3M Company to provide testimony and opinions on questions concerning the use of the Bair Hugger patient warming system in ORs. I am being compensated at the rate of $290 CAD per hour for my work on this case. I have not testified in any cases in the U.S. or Canada in the past four years.

1. INTRODUCTION

Operating room environments are set up to blow large volumes of relatively cool air over patients undergoing surgery. Combined with the patient's medical condition, this can place the patient in a vulnerable situation that could lead to risks of hypothermia. Post-operative surgical site infection from airborne microbes can also be a risk, although it is generally accepted that most surgical site infections are attributable to the patient's skin.

During Orthopaedic surgery in particular, normothermia has been shown to be of effective benefit to patients. Patient warming has been an effective method to achieve normotermia.

A "Bair Hugger" forced air warmer is a system by 3M that achieves patient warming. The Bair Hugger is effectively a blower that heats air and delivers it through a hose. The hose is attached to a perforated blanket that is draped over the patient and blows warms air on the patient's skin. The blanket is then draped, taped, and secured in a manner that directs air exiting the blanket away from the surgical site.

This litigation raises the question whether Bair Hugger could potentially pose an increased risk to patients of infection by introducing bacterial contamination into the surgical wound. This report examines the potential for that risk in context of ventilation design standards and various published studies on the Bair Hugger unit and its use in the operating room.

2. EDUCATIONAL BACKGROUND, TRAINING & EXPERIENCE

My education and training are detailed in my Curriculum Vitae, attached as Exhibit A. I obtained a Bachelor of Applied Science Degree in Mechanical Engineering from the University of Waterloo in 1994 and an Executive Master's Degree in Business Administration in 2000. I started working in the Planning Department at St. Michael's Hospital in 1993 and became the Director of Engineering & Plant Services in 1996, responsible for Hospital Facilities Operation, Maintenance and Redevelopment. I am currently the Senior Director, Planning & Development at the Hospital,

currently responsible for implementing a major redevelopment project at the Hospital.

I started participating in ASHRAE (American Society of Heating, Refrigerating and Air-Conditioning Engineers) in 1994. I held many positions at the ASHRAE Toronto Chapter, including a number of years on the Board and President in 2002-03. In 2003, I started as a member of the Technical Committee (then Task Force) for Healthcare and served as chair of the Technical Committee from 2008-2010, responsible for research activities, educational programs and technical publications related to HVAC scope in the healthcare industry. Since 2003, I have been a member of ASHRAE SSPC 170, standard for ventilation of health care facilities.

I have also participated as a volunteer member of the Canadian Standards Association (CSA) since 1994. In 2003, I was elected Chair of the Healthcare Facilities Technical Committee and held that position until 2014, when I was elected Chair of the Strategic Steering Committee for Healthcare, a position I still hold today. In 2016, I was appointed to the CSA Standards Policy Board. I chaired the inaugural edition of CSA Z8000 Health Care Facilities standard in 2011 and am currently leading the publication of its 2nd edition.

3. OR VENTILATION SYSTEM CHARACTERISTICS

Ventilation systems and designs for health care facilities are intended to provide a comfortable environment for patients, health care workers, and visitors while diluting, capturing and exhausting airborne contaminants including potentially infectious airborne agents.[a] . There is a lot of specialized design that goes into the ventilation systems that serve operating room suites . ASHRAE Standard 170 (*Ventilation of Health Care Facilities*)[a] defines ventilation system design requirements that provide environmental control for comfort, asepsis, and odor in health care facilities. CSA Standard Z317.2 (*Special requirements for heating, ventilation, and air- conditioning (HVAC) systems in health care facilities)*[b] provides requirements for the planning, design, construction, commissioning, operation, and maintenance of HVAC systems in Canadian Health Care Facilities. The proper design, installation, commissioning, operation, and maintenance of HVAC systems can reduce the risk of infection transmission and support positive clinical outcomes among patients.

Some of the factors in the design of a ventilation system that serves an operating room include:

a. TEMPERATURE

Systems shall be capable of maintaining the operating room within the temperature range of 18-23C[b] or 20-24C[a] during normal operation. Lower or higher temperature shall be permitted when patients' comfort and/or medical conditions require those conditions[a.]

Operating rooms often require a range of room temperatures spanning several degrees, regardless of the season, to best facilitate a given procedure or patient condition.

Temperature and humidity plan an important role together to prevent condensation in an operating room. Moisture in a room can pickup bacterial contamination.

Operating room staff are exposed to heat sources, such as operating room lights and are heavily gowned. Temperature control to prevent sweating in staff is an important consideration. Heat from surgical equipment should be considered in managing the cooling load of the OR. Patient warming units such as the Bair Hugger do not contribute significantly to the overall cooling load.

Proper temperature control can also directly impact bacteria growth rates. Many of these grow at a slower rate with lower temperatures.

While most of these factors would drive lower space temperatures in the operating room, keeping the patient warm is important factor for patient comfort, prevention of hypothermia and prevention of nosocomial infection.

b. HUMIDITY

Systems shall be capable of maintaining the operating room within a relative humidity range of 30-60%[b] or 20-60%[a]. Both low and high humidity can create conditions that promote microbial growth.

c. FILTRATION

Systems supplying air to operating rooms are required to provide filtration to remove outdoor or recirculated contaminants at a MERV 14 rating[a,b]. CSA Z317.2 requires filtration of specialized operating rooms, such as orthopaedic and transplant surgeries, to be additionally HEPA filtered.[b] . To my knowledge, no randomized controlled trials have shown a statistically significant difference in infection rates between ORs with HEPA vs. MERV 14 filtration.

d. RELATIVE PRESSURIZATION

Design of the ventilation system shall provide air movement that is generally from clean to less clean areas.[a] Operating rooms are required to be positively pressured[a,b] with respect to adjacent spaces at all times. In other words, all air that enters the room must enter through the ventilation system air supply. While most of the air leaving the room will be through the exhaust/return grilles, some of the air will escape the room openings, such as through doors but infiltration from existing spaces will not occur.

e. AIR CHANGES

Operating rooms require large quantities of air – a minimum total of 20 air changes per hour must be supplied to the volume of the operating room space, consisting of a component of at least 4[a]-6[b] air changes per hour of non-recirculated outdoor air. This high volume of air serves the purpose to dilute and remove contaminants from the space and replace them with high quality, filtered, conditioned air (See Figure 1).

Air Changes per Hour, ach	Time Required for Removal Efficiency of 99%, min	Time Required for Removal Efficiency of 99.9%, min
2	138	207
4	69	104
6	46	69
8	35	52
10	28	41
12	23	35
15	18	28
20	14	21
50	6	8

Source: CDC (2003). **Note:** assumes perfect mixing.

Figure 1 - Effect of Air Change Rates on Dilution times {ASHRAE DESIGN MAUAL}

f. VELOCITY AND DIFFUSER TYPE

Selection of supply diffuser type, exhaust grille location and design of the supply air velocity will determine the airflow pathways and amount of turbulence in the room.

Operating rooms require a diffuser array of Type E non-aspirating diffusers to induce a laminar supply airflow pattern.[a] The average velocity shall be 25-35 fpm.

The room shall be provided with at least two low sidewall return or exhaust grilles spaced at opposite corners or as far apart as possible, with the bottom of these grilles installed approximately 8 in. (203 mm) above the floor.[a]

4. SURGICAL SITE INFECTION (SSI) IN ORTHOPAEDIC CASES IN THE OPERATING ROOM

All surgical operations have the potential for contamination, and the equipment and instruments used, including blades, suction nozzles, needles, light handles and staff apparel such as gloves, can harbour bacteria. The main potential contamination sources are from the skin of the patient and the presence of the theatre medical staff themselves, their movements, and in general their behaviour. It was shown that most primary arthroplasties of the hip and knee are contaminated with bacteria. The organisms are skin commensals which are transferred mainly by the theatre staff to various sites in the operative field.[c]

The source of SSI pathogens is usually the patient's skin, mucous membranes, or bowel and rarely another infected site in the body (endogenous sources). Organisms associated with SSIs vary with the type of procedure and the anatomic location of the operation. Exogenous sources of SSI pathogens (e.g., aerobic staphylococci or streptococci species) can come from members of the surgical team (e.g., from hands, nose, or other body parts); contaminated surfaces in the operating room or the air; and contaminated instruments, surgical gloves, or other items used in the surgery[d]

Other factors have been shown to reduce the incidence of infection, including keeping the number of personnel in the operating room to a minimum and shortening of the duration of surgery.[c]

It is generally agreed that 80 to 90% of HAIs are transmitted by direct contact, with 10% to 20% resulting from airborne transmission (representing 0.4% to 1% of admitted patients)[d]. Transmission of airborne hazards is influenced by factors beyond the control of the engineer that include movement of patients, undiagnosed patients, visitors, concentration of patients, and patient susceptibility. The nature of infectious pathogens, the modes of transmission, the causation of infections, and the relationships to HVAC system design are complicated and not fully understood. Surgical site infections (SSIs) can also be caused by a variety of airborne sources, including deposition of particles either directly on the patient or on the staff and equipment, which are then transferred to the surgical site.[e]

5. BAIR HUGGER POTENTIAL FOR RISKS OF CONTRIBUTING TO SURGICAL SITE INFECTIONS

This report will review the following areas of potential risk:

a. Airborne bacteria passing through the Bair Hugger unit and its filter
b. Disruption of airflow that could increase risk of particles settling in the surgical site

6. FILTRATION IN THE BAIR HUGGER

a. BAIR HUGGER CONTAINS A FILTER

The Bair Hugger units have a filter on the inlet to the unit, filtering all air that passes through the unit. The filters come in different forms for different models. See Figure 2 and Figure 3 below filters on the Bair Hugger 505 and 700 series units. The incorporation of a filter is noteworthy because to my knowledge, there is no ASHRAE or industry requirement to use filters in fan-blowing OR equipment.

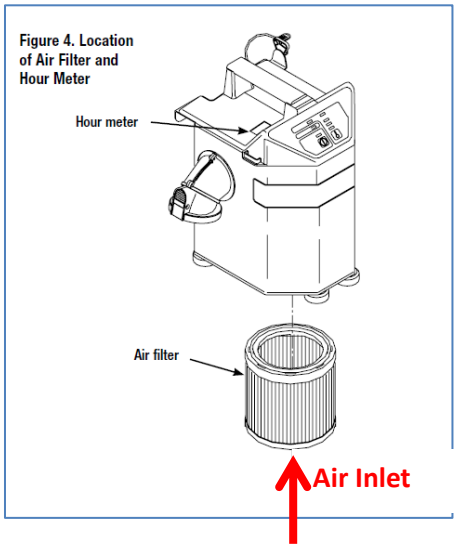

Figure 2 - Bair Hugger 505 Inlet Filter

Figure 3 - Bair Hugger 700 Series Inlet Filter

b. BAIR HUGGER FILTERS ARE TESTED TO ASHRAE 52.2 MERV RATING

Filters are used to collect particles of a certain size in the airstream. Oversized particles are captured in the filter media and smaller particles may pass through the filter, depending on the pore size and thickness of the filter media. Filtration in an operating room environment may protect against the intrusion and spread of airborne pathogens.

ASHRAE Standard 52.2, Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size, is a standard method used to test and rate filters.[f] Particle counts are taken over a range of particle sizes. These particle size ranges are grouped in three categories as shown in Figure 4, E1 (0.3 to 1.0 µm), E2 (1.0 to 3.0 µm) and E3 (3.0 to 10.0 µm).

An "overall" reporting value of an ASHRAE 52.2-evaluated air filter is the expression of the Minimum Efficiency Reporting Value (MERV).

Averaging the Composite Minimum Efficiency for each of the particle size groups will calculate the average Particle Size Efficiency (PSE), and the resulting three percentages (E1, E2, E3) are then used to determine the MERV against Figure 5.

Standard 52.2 Minimum Efficiency Reporting Value (MERV)	Composite Average Particle Size Efficiency, % in Size Range, µm			
	Range 1 (0.3-1.0)	Range 2 (1.0-3.0)	Range 3 (3.0-10.0)	Average Arrestance, %
1	n/a	n/a	$E_3 < 20$	$A_{avg} < 65$
2	n/a	n/a	$E_3 < 20$	$65 \le A_{avg} < 70$
3	n/a	n/a	$E_3 < 20$	$70 \le A_{avg} < 75$
4	n/a	n/a	$E_3 < 20$	$75 \le A_{avg}$
5	n/a	n/a	$20 \le E_3 < 35$	n/a
6	n/a	n/a	$35 \le E_3 < 50$	n/a
7	n/a	n/a	$50 \le E_3 < 70$	n/a
8	n/a	$20 \le E_2$	$70 \le E_3$	n/a
9	n/a	$35 \le E_2$	$75 \le E_3$	n/a
10	n/a	$50 \le E_2 < 65$	$80 \le E_3$	n/a
11	$20 \le E_1$	$65 \le E_2 < 80$	$85 \le E_3$	n/a
12	$35 \le E_1$	$80 \le E_2$	$90 \le E_3$	n/a
13	$50 \le E_1$	$85 \le E_2$	$90 \le E_3$	n/a
14	$75 \le E_1 < 85$	$90 \le E_2$	$95 \le E_3$	n/a
15	$85 \le E_1 < 95$	$90 \le E_2$	$95 \le E_3$	n/a
16	$95 \le E_1$	$95 \le E_2$	$95 \le E_3$	n/a

Figure 4 - MERV PARAMETERS[g]

Range	Size	Group
1	0.30 to 0.40	E1
2	0.40 to 0.55	
3	0.55 to 0.70	
4	0.70 to 1.00	
5	1.00 to 1.30	E2
6	1.30 to 1.60	
7	1.60 to 2.20	
8	2.20 to 3.00	
9	3.00 to 4.00	E3
10	4.00 to 5.50	
11	5.50 to 7.00	
12	7.00 to 10.00	

Figure 5 - Particle Size Ranges[g]

c. BAIR HUGGER FILTER TESTS

ASHRAE 52.2 filter tests were performed on 3 models on Bair Hugger Filters.

i. LMS Technologies Lot#4670185

LMS Technologies, tested a filter on April 28, 2016 using the ASHRAE 52.2 method. The filter was a white mini pleated cylindrical filter from a Bair Hugger model 505. The test results indicate the model 505 unit has an inlet filter classified as a MERV 14.

ii. LMS Technologies Lot#4640927

LMS Technologies, tested a filter on April 28, 2016 using the ASHRAE 52.2 method. The filter was a white mini pleated filter from a Bair Hugger model 750. The test results indicate the model 750 unit has an inlet filter classified as a MERV 14.

iii. 3M Maplewood RD-TEST-PW-05-286536

3M Maplewood tested a filter on August 25, 2016 using the ASHRAE 52.2 method. The filter was a white mini pleated filter from a Bair Hugger model 775. The test results indicate the model 775 unit has an inlet filter classified as a MERV 14.

d. DISCUSSION OF FILTRATION IN THE BAIR HUGGER

As mentioned above, ASHRAE 170 requires a MERV 14 filter in air handling systems supplying air to an operating room, providing a an airstream over the patient through non-aspirating diffusers.

In a typical operating room, there exist a number of pieces of equipment that contain fans in addition to the use of a Bair Hugger warming system. For example, a number of microprocessor based pieces of components have small cooling fans to keep components from overheating. As noted, I am not aware of any standards that exist for filtration on equipment mounted fans.

A simple reduction of 70-90% of airborne pathogens may be sufficient to reduce risks to an acceptable minimum.[h] Nonetheless, the Bair Hugger systems have intake filters at a MERV 14 rating, equivalent to the required air supply for the operating room. The use of a MERV 14 filter in the Bair Hugger system, while not required by any standards, should effectively capture microbes drawn into the warming unit intake.

It is important to note that neither MERV 14 nor HEPA filters can claim 100% effectiveness at preventing the passage of particles. There is always a small chance that a particle may pass through any filter. Understanding these limitations, ASHRAE nevertheless recommends the use of filters in the MERV 14 range as appropriate for controlling bacteria.[e]

7. ALLEGED IMPACTS OF BAIR HUGGER ON AIRFLOW IN AN OPERATING ROOM

a. LAMINAR AIRFLOW IN OPERATING ROOMS

The standard for operating room ventilation is to provide air supply systems based on laminar flow diffuser arrays (Group E). Laminar diffuser systems control airborne contamination in operating rooms by providing a downward wash of clean supply air at relatively low velocity.

Laminar airflow has generally been associated with decreased air microbial contamination in clean surgery[i]. A recent study of 80 orthopaedic surgeries showed that the absence of a turbulent-free laminar airflow resulted in significantly increased bacterial counts.[j]

The most effective laminar diffuser systems would see the entire ceiling filled with laminar flow diffusers and all air exhausting through low baseboard return grilles (See Figure 6). The practice of covering the entire ceiling in diffusers is not only impractical for an operating room, but the supply air volumes would be well in excess of code requirements.[k]

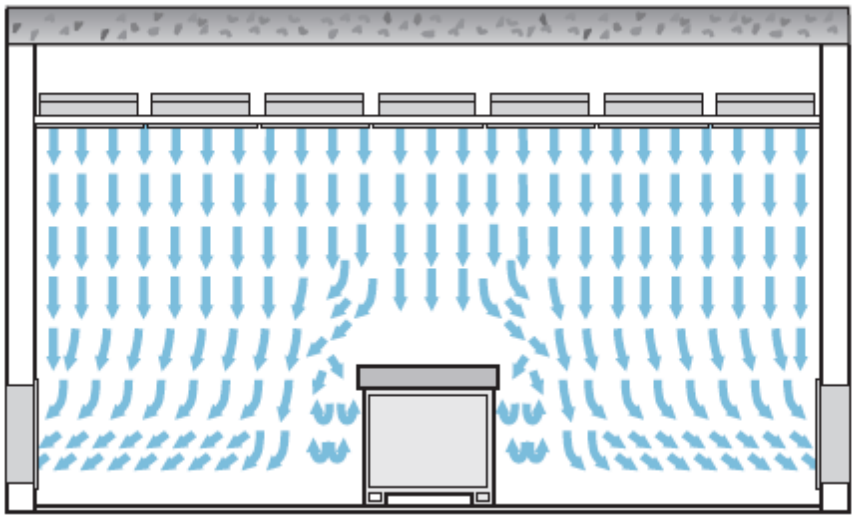

Figure 6 - Operating Room Laminar Flow System with Full Ceiling Coverage[k]

The laminar diffusers are set into arrays intended to create a uniform laminar airflow profile covering a critical zone to continuously sweep contaminants down and away from the patient and surgical staff.[e]

Velocity of supply air is an important factor of a properly designed laminar airflow supply system in an operating room. At flow rates below 25 fpm, the airflow velocity may not be sufficient to prevent the possibility of surgical zone contamination due to entrainment of the recirculating room air. In contrast, air flow exceeding 45 fpm may increase the potential for re-entrainment of particulates and debris that may have settled on the floor.[k] Higher velocities in the laminar airflow also increase the risk of particle impingement on the surgical site by overcoming the thermal plume of the surgical site .[l]

Reducing the size of the laminar diffuser array opens space for other ceiling-mounted equipment (lights, booms, gas columns, etc.). At minimum, laminar flow diffusers should cover 70% of the ceiling area directly above the area defined by the surgical table and a 12 in. offset[a]. This minimum requirement will usually not satisfy minimum room air change requirements and additional supply diffusers beyond the primary diffuser array area are most often necessary.[k]

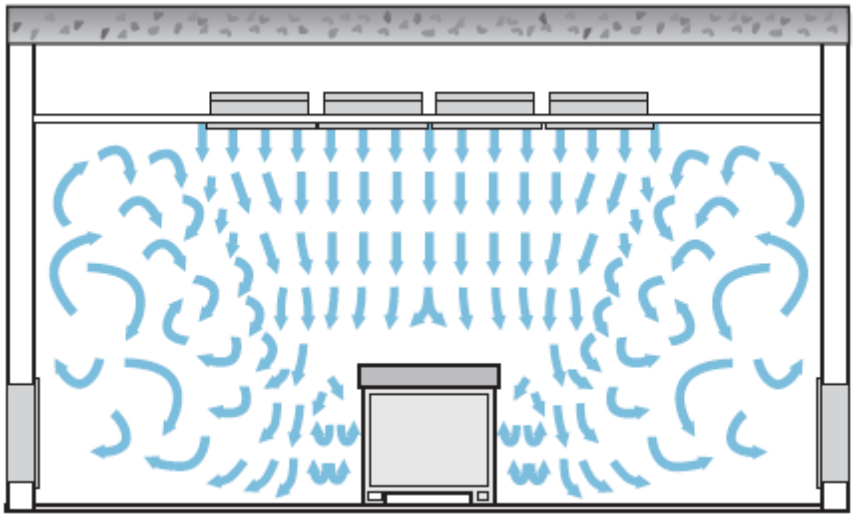

Figure 7 - Operating Room Laminar Airflow Diffuser Array[k]

b. TURBULENCE IN LAMINAR FLOW DESIGNED OPERATING ROOMS

Note that although the initial airflow from the diffusers is in a laminar formation, once it passes the table it develops a more turbulent formation outside of the primary diffuser array at the perimeter of the room (see Figure 7).

Although laminar flow diffusers are considered by many to be non-aspirating air outlets, some entrainment of room air still occurs within the first 3 to 6 in. below the diffuser face. The holes in the perforated face act as individual air jets, causing air to accelerate as it passes through the smaller free area. Once through the perforated face of the diffuser, the air jets will expand, coalesce and decelerate. By the time the air mass is more than 6 in. from the diffuser face, the air velocity profile will be more consistent and the actual velocity of the supply air will be much closer to the average velocity. (When the actual air velocity is in the 25 to 35 cfm/ft2 range there is minimal entrainment of room air.)[k]

Laminar airflow has been promoted on the basis of quality criteria obtained in empty OR's. However, during operations, many events may disrupt the laminarity of airflow, including the presence of surgical staff at the surgical site, lighting and door opening.[i]

In particular, the operating lights and surgical staff represent a large heat density in the middle of the room. Figure 8 lists the loads of various heat sources typically found in an operating room. Particulates could get caught in buoyant plumes created by these heat-dissipating objects, at which point control of them is lost. (See Figures 9 and 10) However, if a laminar flow type system is employed, the particles should be driven by the flow to be exhausted. Ideally then, the array size should be large enough to cover the main heat-dissipating objects.[l]

Operating Room Loads	
Heat Source	**Design Conditions (Btu/h)**
Patient	160
Surgical Team (4)	1200
Support Staff (2)	600
Anesthesia equipment	900
LCD monitors	850
Surgical lights	1500
Overhead lighting	2400
Total	7610

Figure 8 - Heat Loads in OR[k]

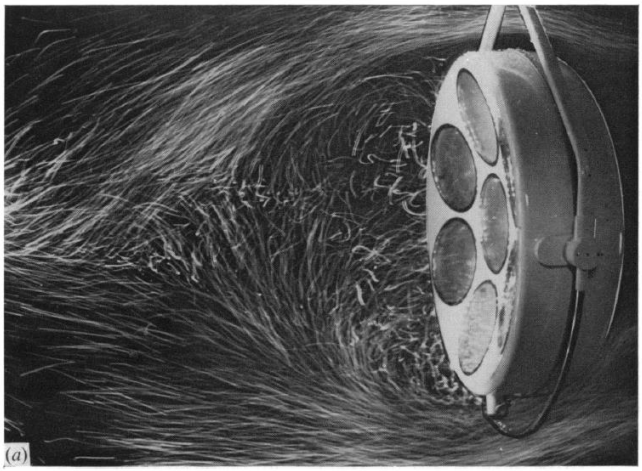

Figure 9 - Airflow disruption of a surgical light[m]

Figure 10 - Airflow disruption of surgical staff[m]

c. POTENTIAL RISK OF BAIR HUGGER DISRUPTING SUPPLY AIRFLOW

The Bair Hugger blows warm air through a perforated blanket. Air eventually escapes primarily through the head and neck area of the patient. Adhesive strips help seal edges of the sterile drape adjacent to the surgical site, so that escaping air does not blow directly in the direction of a surgical site.

A question has been raised that forced air warming devices pose surgical site infection risk by disrupting the laminar airflow, allowing bacteria to enter the surgical site or impede the ventilation systems ability to remove contaminants from the surgical site.[n]

i. USE OF BUBBLES TO STUDY PARTICLES IN AIRFLOW

Albrecht[n,o] and Legg[p] performed studies, whereby bubbles were generated to simulate the airflow patterns of bacteria attached to particles with and without a forced air warming system on. This was based on their hypothesis that smaller airborne particles ≤10 µm, such as free-floating bacteria and skin cell fragments, had similar airborne characteristics to the neutrally buoyant detergent bubbles studied (i.e., appreciable suspension times).[n]

By following bubble patterns, Albrecht claims that forced-air warming established convection currents that mobilized resident air from non-sterile areas such as the floor and under the anaesthesia/surgery drape into the surgical site. The upward mobilization of floor-level and under-drape air could potentially compromise the sterility of the surgical site, as air from these locations is typically laden with pathogens shed from surgical staff.[o]

Legg admittedly stated that his study did not show that forced-air warming increased the risk of infection – he only claims that in certain types of theatre set-up it can significantly disrupt unidirectional airflow and draw particles from the potentially contaminated area below the sterile surgical field.

The ability of a bubble to accurately represent a bacteria-laden particle in air is questionable. First of all, the size of the bubble is significantly larger, presenting a greater surface area to be impacted by airflow. Studies have also shown that bubbles are generally not reliable to accurately represent airflow.[q] When the bubbles are generated, they also have a starting velocity when they exit the bubble generator wand that may contribute to inaccuracies not representing true airflow impacts.

ii. PARTICLE CHARACTERISTICS

The ability of a particle to remain airborne, is dependent on the size and density of the particle. The size distribution of airborne particles carrying microorganisms is determined by two opposing factors, gravity, which tends to eliminate the large particles, and the

chance that a particle will carry a viable organism, which is likely to increase with the size of the particle.[r]

The sizes of typical nosocomial pathogens are listed in Figure 11.

TABLE 8.2

Airborne Nosocomial Pathogen Removal Rates

Microbe	Size (μm)	MERV Filter Model Filtration Efficiency (%)								
		6	8	9	10	11	12	13	14	15
Parvovirus B19	0.022	21	32	35	40	52	72	89	97	98
Rhinovirus	0.023	21	31	34	39	51	70	88	97	98
Coxsackievirus	0.027	19	29	31	36	47	66	85	96	97
Norwalk virus	0.029	18	27	30	35	45	64	84	95	97
Rubella virus	0.061	11	16	18	21	28	43	62	82	84
Rotavirus	0.073	9	14	15	18	24	38	57	77	79
Reovirus	0.075	9	14	15	17	24	37	56	77	79
Adenovirus	0.079	9	13	14	17	23	36	54	75	77
Influenza A virus	0.098	7	11	12	14	19	31	48	69	71
Coronavirus (SARS)	0.11	6	10	11	13	18	28	45	66	68
Measles virus	0.158	5	8	9	10	15	24	38	59	63
Mumps virus	0.164	5	8	9	10	14	23	38	58	63
VZV	0.173	5	8	8	10	14	23	37	58	63
Mycoplasma pneumoniae	0.177	5	7	8	10	14	23	37	58	63
RSV	0.19	5	7	8	9	14	23	37	58	64
Parainfluenza virus	0.194	4	7	8	9	14	23	37	58	64
Bordetella pertussis	0.245	4	7	8	9	14	23	38	61	68
Haemophilus influenzae	0.285	4	8	9	10	16	25	41	64	73
Proteus mirabilis	0.494	7	13	15	16	25	39	60	84	92
Pseudomonas aeruginosa	0.494	7	13	15	16	25	39	60	84	92
Legionella pneumophila	0.52	7	14	16	17	27	41	62	86	93
Serratia marcescens	0.632	9	17	21	22	33	49	71	92	97
Mycobacterium tuberculosis	0.637	9	18	21	22	33	49	72	92	97
Klebsiella pneumoniae	0.671	10	19	22	24	35	52	74	93	98
Corynebacterium diphtheriae	0.698	10	20	24	25	37	54	76	94	98
Streptococcus pneumoniae	0.707	11	20	24	26	37	54	77	94	98
Alcaligenes	0.775	12	23	27	29	41	59	81	96	99
Neisseria meningitidis	0.775	12	23	27	29	41	59	81	96	99
Staphylococcus aureus	0.866	14	26	31	33	45	64	85	97	99
Staphylococcus epidermis	0.866	14	26	31	33	45	64	85	97	99
Staphylococcus pyogenes	0.894	14	27	32	34	47	66	86	97	99.5
Mycobacterium avium	1.118	19	35	41	44	57	76	93	99	99.8
Nocardia asteroides	1.118	19	35	41	44	57	76	93	99	99.8
Acinetobacter	1.225	21	39	45	48	61	80	94	99	99.9
Enterobacter cloacae	1.414	24	45	52	55	68	85	97	99	99.9
Enterococcus	1.414	24	45	52	55	68	85	97	99	99.9
Haemophilus parainfluenzae	1.732	30	53	61	65	76	92	98	99	99.9
Clostridium difficile	2	34	59	66	71	81	95	99	99	99.9

Continued

Figure 11 - Airborne Nosocomial Pathogen Sizes[h]

TABLE 8.2 (*Continued*)

Airborne Nosocomial Pathogen Removal Rates

Microbe	Size (μm)	MERV Filter Model Filtration Efficiency (%)								
		6	8	9	10	11	12	13	14	15
Pneumocystis carinii	2	34	59	66	71	81	95	99	99	99.9
Fugomyces cyanescens	2.12	35	61	69	73	83	96	99	99	99.9
Histoplasma capsulatum	2.236	36	63	70	76	85	96	99	99	99.9
Pseudallescheria boydii	3.162	44	71	78	86	91	99	99	99	99.9
Scedosporium	3.162	44	71	78	86	91	99	99	99	99.9
Penicillium	3.262	44	72	79	87	91	99	99	99	99.9
Aspergillus	3.354	45	72	79	87	92	99	99	99	99.9
Coccidioides immitis	3.464	45	73	80	88	92	99	99	99	99.9
Cryptococcus neoformans	4.899	49	75	82	91	94	99	99	99	99.9
Clostridium perfringens	5	49	75	82	91	94	99	99	99	99.9
Rhizopus	6.928	50	75	82	92	94	99	99	99	99.9
Mucor	7.071	50	75	82	92	94	99	99	99	99.9
Trichosporon	8.775	50	75	82	92	94	99	99	99	99.9
Alternaria alternata	11.225	50	75	82	92	94	99	99	99	99.9
Fusarium	11.225	50	75	82	92	94	99	99	99	99.9
Blastomyces dermatitidis	12.649	50	75	82	92	94	99	99	99	99.9

Note: Size = logmean diameter. Filter performance may vary with manufacturer's model.

Figure 11 (cont'd)

The science of controlling infections caused by airborne microorganisms is a complex mixture of engineering, particle physics, microbiology, and medicine. The rates at which particles settle are a function of their size, shape, density, and of course, air movement. Turbulence within a room increases the residence time of larger particles in the air, hence the desire for laminar airflows in operating rooms.

Particles larger than 0.3 um in diameter will tend to settle out over time, these include most bacteria, fungal spores, dust particles, skin squames and droplets or droplet nuclei, which may include clumps of viruses or bacteria. Particles smaller than 0.3um will tend to remain suspended in air and are subject to the effects of turbulence and diffusion.[h] The natural buoyancy of the bubbles used in the studies by Albrecht and Legg would therefore not be representative of these larger particles.

Albrecht[o] concluded the release of heat may generate convection currents that rise against the downward airflows, drawing non-sterile floor-level air into the surgical site. Given the difference between particles in question and the bubbles in their ability to overcome gravity, it seems an unlikely that this study can draw a conclusion that bacteria-laden

particles will be lifted off the floor.

iii. REVIEW OF PARTICLE COUNTING STUDIES

LEGG (2012)[s]

In another study by Legg (2012), bubbles were not used but particles of three sizes (0.3um, 0.5um and 5.0um) were measured using a HandiLaz handheld counter positioned 10cm over the surgical site. The authors reported an increase of 1.1C in temperature with forced air warming and considerable increase in the number of smaller particle sizes. The change in particle counts of the 5.0um size was negligible. Legg reported that "bacteria require particles to transport them and although we are unable to confirm if any of the particles were transporting bacteria, the significant increase in the number of particles that we found in this study at the surgical is of concern". The largest increase was in the 0.3um size – which is approximately three times smaller than most bacteria of concern. Moreover, most bacteria-carrying particles, including skin squames, would be much larger—in the range of 5.0 um. As noted, Legg et al. did not show a meaningful increase in particles of that size with Bair Hugger use.

SESSLER (2011)[t]

Sessler studied particle counts also at 10cm over the surgical site, in the range of 0.5-1.0um. This study concluded there was no significant increase in number of particles of this size with forced air warming turned on.

MCGOVERN (2009)[u]

This study again counted particles of sizes ranged 0.3-5.0um in size above the surgical site using a Handilaz Mini handheld particle counter. The experiments showed no notable increase in particle count when a forced air warming device was used in the normal intra-operative manner. There was an increase in local particle counts only when the surgeon entered the operative field, from outside the laminar flow boundary.

MERMARZEDEH (2010)[v]

In a CFD study, NIH analysed laminar airflow disruption and room airflow patterns to determine the effect of squame impingement from personnel surrounding the operating table as a source of surgical wound infection. It was found that the downward velocity from the ceiling laminar diffuser is slightly less strong with the forced air warmer operating than when the air warmer is off. The squame plots show that particles are cleaned away from the patient by the airflow from the laminar diffuser no matter if the forced air warmer is on or off.

NIH concluded that in both scenarios there is zero percent deposition on the patient for the contaminant sources and the heat generated by the patient provides some protection. If the operating room ventilation system is designed properly, contaminating particles from staff around the patient will not impinge on the surgical wound due to "thermal plume" dynamics. Forced-air warmers seem to cause minimal disruption to laminar airflow systems that help protect the surgical site from contaminated particles sourced from surgical staff.

d. THERMAL PLUME AS A PROTECTIVE BARRIER

It is important to note that the purpose of the laminar airflow in an operating room is not to "flush" the surgical site, but rather to create a protective cocoon around the site, helping to prevent contaminants from outside the field from entering the surgical site. In fact from Figure 12, it has been shown that the thermal plume from the surgical site exerts force up against the downward flow and diverts it around the wound, if the ventilation has been designed at the right velocity. Staff introduce a source of contamination and a number of obstructions disrupt the laminar flow such that it is never truly laminar and it is possible that some contaminants are carried by the airflow. If air velocity is too high, the laminar airflow could overcome the thermal plume and introduce contaminants into the surgical site.

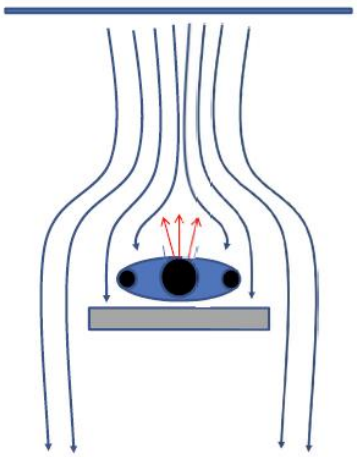

Figure 12 - Thermal plume of surgical site

As seen in Figure 13, a forced air warming device could have a similar protective effect as the surgical site plume, the heat of the blanket providing an upward force bucking against the laminar flow field within a very short distance above the blanket.

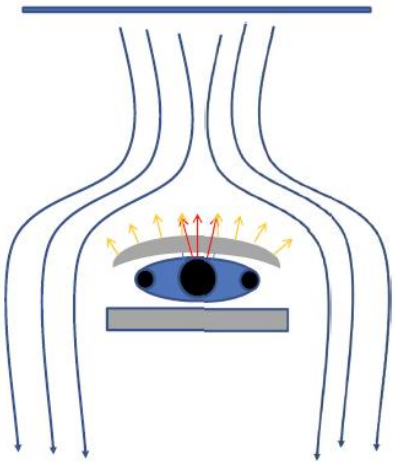

Figure 13 - Thermal plume of surgical site and warmer

SETTLES (2017)[w]

Using Schlieren imaging technique, Settles showed that the length scale of the micro-jet exhaust of warm air from the blanket is on the order of a few centimeters. Above that, it would thus have no residual buoyancy to buck the downflow of clean air that opposes any such motion. Settles also concluded that the same lack of residual buoyancy would not result in lifting particles off the floor to the level of the surgical table.

e. ATTEMPTS TO USE PARTICLE COUNTING TO PREDICT BACTERIAL CONTAMINATION

Several studies have proposed that the microbiological quality of the air in operating theatres be indirectly evaluated by means of particle counting, a technique derived from industrial clean-room technology standards, using airborne particle concentration as an index of microbial contamination.[x,{LANDRIN 2005}

Interpretation of particle count is based on the theory that particles may shed organisms, and their number might correlate with airborne microbial contamination. However, the association between particles and organisms is far from being clearly established.[i]

In my experience, the absence of an increase in particles can be a good indication of the absence of an increase in bacterial contamination, as the bacteria travels on the particles. However, although

the inverse is a good trigger for signaling further investigation, it is not conclusive in determining the degree of microbial bioburden.

8. REVIEW OF STUDIES TO MEASURE BACTERIAL CONTAMINATION

The following studies investigated whether the use of a forced-air warming increased actual airborne bacterial contamination (as opposed to particles or helium bubbles).

AVIDAN (1997)[y]

Nine forced air warmers were turned on and agar plates were placed by the outlet. Four of the warmers produced grew potentially pathogenic organisms. Three of the warmers were swabbed and sites of colonisation were found in their outlet hoses. However, when the warmers were set to blow through perforated blankets, no growth occurred. 3M specifically instructs users not to use the Bair Hugger system without a blanket in place.

RICHARD (2017)[z]

Contaminated OR surfaces can increase the risk of orthopaedic infections, particularly after procedures in which hardware implantation and instrumentation are used. This study aimed to highlight the utility of 'ATP bioluminescence' technology as a useful technique in detecting the degree of contamination within the sterile OR environment.

First used in the food industry, adenosine triphosphate (ATP) bioluminescence monitoring has been become broadly applicable in the healthcare setting to provide rapid results regarding hospital cleanliness with improved benefits in the control of surface contamination and application of corrective action against poor hygiene.

A total of 13 different surfaces were sampled once in each room: the operating room (OR) preparation table (both pre- and postdraping), OR light handles, Bovie machine buttons, supply closet countertops, the inside of the Bair Hugger hose, Bair Hugger buttons, right side of the OR table headboard, tourniquet machine buttons, the Clarksocket attachment, and patient positioners used for total hip and spine positioning.

The relative light units (RLUs) obtained from each sample were recorded and data were compiled and averaged for analysis. These values were compared with previously published ATP benchmark values of 250 to 500 RLUs to define cleanliness in both thehospital and restaurant industries.

Although all surfaces had some level of bioburden, some were lower than the 200-500 RLU cleanliness threshold and some were significantly higher. The inside of the Bair Hugger hose was under the threshold and thus clean relative to other surfaces in the OR. The highest surfaces of contamination included the OR table headboard, the OR prep table, OR light handles and common touch points such as equipment buttons and computer keyboards.

ZINK (1993)[aa]

Culture plates were placed directly on the simulated patient's abdomen. Eight simulated procedures were analysed with a forced air warmer turned off for the first 2 hours and then on for the next 2 hours. No significant differences in the number of bacterial colonies were observed between the two study periods.

SHARP (2002)[bb]

Air samples were taken 30 cm from the simulated operating site using the Sampler Air System. The apparatus samples air at 180 l/min directly on to tryptone glucose yeast agar plates. The plates were incubated at 37ºC for 48 hours and the number of colonies counted.

No colonies were grown in any of the groups tested and results suggest that the patient warming system does not influence bacterial counts at the operating site in an ultraclean air-ventilated theatre. The theoretical risk of airflow under the blanket passing CFUs from the patient to the operating area was notconfirmed by this study.

HUANG (2003)[cc]

Sixteen consecutive patients undergoing aortic surgery with prosthetic graft insertion were prospectively studied. All operating theatre air specimens (sites A1–A3) exhibited a decrease in colony counts at the end of surgery (mean reduction 36.4%). The exhaust air (sites B1 and B2) colony counts also decreased at the end of surgery, although the size of the reduction was much less (mean reduction 9.5%).

The exhaust air from beneath the surgical drapes, which had passed over the patient’s skin, showed a decrease in the number of bacterial counts at the end of surgery, and this demonstrated that there was no increase in air contamination associated with the Bair Hugger patient warming system

None of the patients developed postoperative wound or prosthetic infections during a 6-month follow-up period.

ALBRECHT (2007)[dd]

Study was performed at Regina Surgery Center (MN). Liquid extraction from hoses resulted in the presence of viable organisms on inside surface of the hose. Particle impaction detected few, if any, airborne CFU emanating from the convective warmers.

ALBRECHT (2007)[ee]

This study adds another 2 hospitals (St Cloud, DC) to the study above. Swabbing of hose outlets, liquid extraction from hoses and impact plates were placed after the warmer exhausts. Although some presence was found inside the hoses, impact plates did not show any CFUs from the airstream exiting

the hose.

ALBRECHT (2008)[ff]

Albrecht conducted research in 5 hospitals within the twin cities (including the three above). Swabbing and rinsing of the units had CFUs present, but the impaction plates showed no growth from the Bair Hugger airstream.

MCGOVERN (2009)[u]

Simulated operations in a laminar flow operating theatre. Bacteria samples taken with settle plates. These was no notable increase in bacterial count when the air warming unit was on. Concluded that forced air warming devices do no increase the bacterial count in the vicinity of the operative filed.

The outlet hose was swabbed and no microorganisms were found.

MORETTI (2009)[gg]

The level of bacterial contamination of the air in the operating theatre was quantified with and without the use of the Bair Hugger, during the course of 30 total non-cemented hip implants performed in patients with osteoarthritis.

The air sampler used was an Active Surface Air System (SAS; Aquaria, s.r.l, Italy), a single plate sampling system that directs a constant flow of air on to an agar plate

A significantly increased bacterial load was recorded after the patient's entry into the operating theatre. The increased bacterial load found after application of a bodywarming system appears to be comparable to, or lower than, the load present at the time of placement of the patient on the operating table (see Figure 14). This provides further confirmation of the literature data supporting the contention that the main potential contamination factor in the operating theatre is the presence of the theatre medical staff themselves, their movements, and in general their behaviour.

In none of the surgical patients did a nosocomial infection develop.

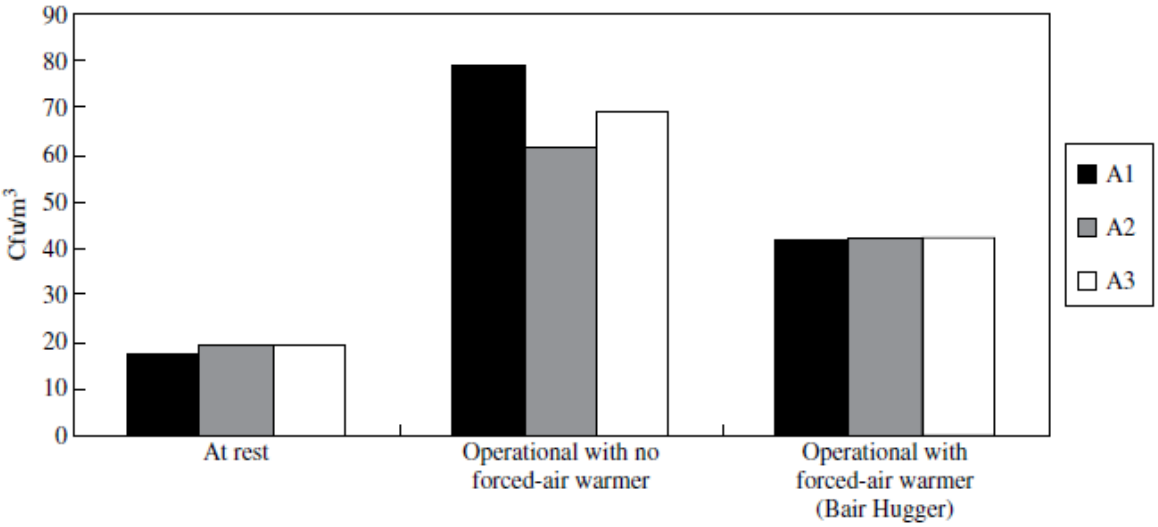

Figure 14 - Moretti sample results[gg]

OCHIPINTI[hh]

Surgical drapes of 100 patients undergoing clean surgical procedures were swabbed with aerobic culturettes at the beginning and end of surgery. Samples cultured on Trypticase soy agar. There was no significant difference in the number of contaminated surgical drapes between the Bair Hugger and control groups.

OGUZ (2017)[j]

The aim of the study was to determine the influence of four intraoperative factors – use of laminar airflow, duration of surgery, number of health professionals present and use of forced air - on airborne bacterial contamination, measured by 6 sedimentation plates at standardized locations in the OR. Eighty patients undergoing minor orthopedic surgery were included in the study. Surgery took place in ORs with and without a unidirectional turbulent free laminar airflowsystem, patients were randomized to warming with a forced air or an electric warming system.

The study showed that in the setting of minor orthopedic surgery an OR with laminar airflow, a reduction of surgery time, by trend a reduced number of personnel present, but not the choice of a non-forced air patient warming system was associated with a decreased airborne sedimentation.

9. SUMMARY OF OPINIONS

a. The Bair Hugger unit contains an intake filter that is tested to perform at MERV 14 rating. MERV 14 filtration is effective at controlling airborne bacteria. Given that ASHRAE Standard 170 requires a MERV 14 filtration on supply air, this is an appropriate filter to include on the

unit.

b. The laminar flow characteristic in an operating room is an important design feature to provide a protective field from infiltration of possible contamination. However, it should be recognized that there are many sources of heat generation and physical obstruction typically within the laminar airflow field that disrupt it and can cause some turbulence.

c. Bubbles are not a reliable simulation for particle movement in an operating room.

d. The thermal plume of the surgical site offers a protective force that helps prevent contaminated particles from settling in the surgical site from the air, if the ventilation system is designed properly with the right air velocity. The Bair Hugger may enhance the protective effect of the patient's thermal plume.

e. Particle count is not a good surrogate for bacterial count.

f. Some studies have found positive bacteria swabs in the outlet hose of the Bair Hugger. However, bacterial contamination has not been demonstrated to propogate into the operating room when used as recommended attached to a blanket. It has also been shown that the level of contamination inside the hose is relatively clean and not as significant as the contamination of frequent touch points in the OR.

g. Overall studies that were reviewed do not indicate increased risk of bacterial contamination or post surgical infection rates associated with the use of a Bair Hugger forced air warming device.

These opinions are held to a reasonable degree based on the information presented. I reserve the right to amend and/or supplement this report and these opinions if additional information/context is presented to me.

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June 2, 2017

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